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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/230,929      | 04/02/1999  | JURGEN KLEINSCHMIDT  | 4121-107            | 3634             |

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/230,929

Applicant(s)

KLEINSCHMIDT ET AL.

Examiner

Joseph T. Voitach

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
 2. ☒ The proposed amendment(s) will not be entered because:  
 (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☒ they raise the issue of new matter (see Note below);  
 (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
 6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
 7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 14-25, 27, 29, 38-51, 53-61, 66.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
 9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.  
 10. ☐ Other: \_\_\_\_\_

*Joe Voitach*  
 AV1632

Continuation of 2. NOTE: No specific support for the proposed amendment of 'a part of the early papillomavirus gene has been deleted thereby rendering the early papillomavirus polypeptide non-transforming' and while the specification provides support for making chimeric proteins with the E6 and E7, it does not provide support for all early genes nor specific guidance to what specific deletions will render the proteins non-transforming. The proposed amendment would require a new search and consideration under 35 USC 12, first paragraph, for new matter and regarding the description and enablement of the proposed amendment.

Continuation of 5. does NOT place the application in condition for allowance because: With regard to Applicants' arguments in traverse of the rejection made under 35 USC 112, second paragraph, Examiner would agree that certain viral E6/E7 participate in the transformation process; however, transformation is a process requiring other steps and events to 'transform' a cell. Examiner does not dispute the specific teachings cited by Applicants but each of these serves to support that E6/E7 are relevant and involved in the process of transformation but that they are not sufficient alone for transformation. Examiner acknowledges that the patentee can be his/her own lexicographer and that the specification can be used to define a term, however as noted in the previous office actions the specification does not provide for such a definition. Importantly, previous claims encompassing encoding the entire E6/E7 as nontransforming proteins contradict Applicants' arguments and position that one of these proteins alone would be considered non-transforming. With respect to Applicants' arguments in traverse of the rejection made under 35 USC 103, it is noted that arguments directed to the proposed amendments are not considered because the amendment has not been entered. With respect to the analysis of the teaching of each of the individual references, it is noted that Applicants do not argue that each of the claimed embodiments are not anticipated, rather the rejection fails to provide adequate motivation and the references specifically teach away from the claimed invention. The cited art must be reviewed as a whole, not what they provide individually. Applicants rely on specific limitations and intended uses of claimed inventions that are not necessarily limitations that would be recognized by the skilled artisan for the invention as a whole. As noted in the final office action, Applicants' arguments are not found persuasive because the motivation to combine the teaching of the cited references is provided by art recognized problems.